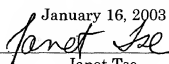


1644
P#12
Patent Docket P1795R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Wyns Pun Lee et al. Serial No.: 09/738,540 Filed: December 14, 2000 For: TREATMENT METHOD	Group Art Unit: 1644 Examiner: M. Haddad CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on January 16, 2003  Janet Tse
--	--

TRANSMITTALAssistant Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated July 16, 2002, applicants submit herewith courtesy copies of the Form PTO-1449 (4 pages) and the 85 references cited thereon. The Form PTO-1449 and copies of the 85 cited references were originally submitted to the Patent Office along with the IDS filed on June 28, 2001. Also enclosed is a courtesy copy of the stamped return postcard indicating the Patent Office's receipt of the above-mentioned documents.

Respectfully submitted,
GENENTECH, INC.

RECEIVED

JAN 8 2003

Date: January 16, 2003

By: Lee Tan

TECH CENTER 1600/2900

Lee K. Tan, Ph.D.

Reg. No. 39,447

Telephone No. (650) 225-4462



09157

PATENT TRADEMARK OFFICE



In re Application of: Wyne P. Lee et al.
Serial No.: 09/738,540
Filed On: 14 December 2000
Mailed On: June 28, 2001

Docket No.: P1795R1
By: Lee K. Tan
Reg. No.: 39,447

1/11/01

The following has been received in the U.S. Patent Office on the date stamped:

- ☒ Information Disclosure Statement
- ☒ Form 1449 with 85 References
- ☒ Certificate of Mailing
- ☒ A copy of the PCT Search Report



RECEIVED

JAN 23 2003

TECH CENTER 1000/2800

FORM PTO-1449

JAN 21 2003

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738,540

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	1 5,336,603	09.08.94	Capon et al.			
	2 5,514,582	07.05.96	Capon et al.			
	3 5,565,335	15.10.96	Capon et al.			
	4 5,594,106	14.01.97	Black et al.			
	5 5,605,690	25.02.97	Jacobs et al.			
	6 5,629,285	13.05.97	Black et al.			
	7 5,654,407	05.08.97	Boyle et al.			
	8 5,656,272	12.08.97	Le et al.			
	9 5,698,195	16.12.97	Le et al.			
	10 5,712,155	27.01.98	Smith et al.			
	11 5,795,967	18.08.98	Aggarwal et al.			
	12 5,919,452	06.07.99	Le et al.			
	13 5,945,397	31.08.99	Smith et al.			
	14 5,981,701	09.11.99	Wallach et al.			
	15 5,985,620	16.11.99	Sloud			
	16 5,994,510	30.11.99	Adair et al.			
	17 5,997,867	07.12.99	Waldmann et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
	18 212,489 B1	30.11.94	EPO			
	19 218,868 A3	22.04.87	EPO			
	20 288,088 B1	09.03.94	EPO			
	21 308,378 B1	30.11.94	EPO			
	22 398,327 B1	15.03.95	EPO			
	23 412,486 B1	30.11.94	EPO			
	24 433,900 B1	20.09.95	EPO			
	25 526,905 A2	10.02.93	EPO			
	26 WO 00/56363	28.09.00	PCT			
	27 WO 92/07076	30.04.92	PCT			
	28 WO 92/11383	09.07.92	PCT			
	29 WO 92/13095	06.08.92	PCT			
	30 WO 92/16553	01.10.92	PCT			
	31 WO 97/29131	14.08.97	PCT			
	32 WO 98/22137	28.05.98	PCT			
	33 WO 98/23761	04.06.98	PCT			

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-144

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738,540

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 34 Aderka et al., "The possible role for tumor necrosis factor (TNF) and its natural inhibitors, the soluble-TNF receptors, in autoimmune diseases" *Isrl. J. Med. Sci.* 28:126-130 (1992)
- 35 Bringman and Aggarwal, "Monoclonal Antibodies to Human Tumor Necrosis Factor Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes" *Hybridoma* 6:489-507 (1987)
- 36 Buchan et al., "Interleukin-1 and tumour necrosis factor mRNA expression in rheumatoid arthritis: prolonged production of IL-1 α " *Clin. Exp. Immunol.* 73:449-455 (1988)
- 37 Campana et al., "Human leukocyte function-associated antigens on lympho-hemopoietic precursor cells" *European Journal of Immunology* 16(5):537-542 (May 1986)
- 38 Chen et al., "Chondrocyte transplantation and experimental treatment options for articular cartilage defects" *American Journal of Orthopedics* 26(6):396-406 (1997)
- 39 Desroches et al., "Regulation and Functional Involvement of Distinct Determinants of Leucocyte Function-Associated Antigen 1 (LFA-1) in T-Cell Activation In Vitro" *Scand. J. Immunol.* 33:277-286 (1991)
- 40 Dustin and Springer, "Lymphocyte function-associated antigen-1 (LFA-1) interaction with intercellular adhesion molecule-1 (ICAM-1) is one of at least three mechanisms for lymphocyte adhesion to cultured endothelial cells" *Journal of Cell Biology* 107(1):321-331 (Jul 1988)
- 41 Engelmann et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity" *Journal of Biological Chemistry* 264:11974-11980 (1989)
- 42 Engelmann et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine" *Journal of Biological Chemistry* 265(3):1531-1536 (1990)
- 43 Exley et al., "Monoclonal antibody to TNF in severe septic shock" *Lancet* 335:1275-1276 (1990)
- 44 Fekete et al., "Involvement of Lymphocyte Function-Associated Antigen-1 (LFA-1) But Not ICAM-1 in a Radioactive Leukocyte Cell-Mediated Immunity (LA-CMI) Assay" *J. Clin. Lab. Immunol.* 31:145-149 (1990)
- 45 Feldmann, M., "What is the Mechanism of Action of Anti-Tumor Necrosis Factor- α Antibody in Rheumatoid Arthritis?" *Int. Arch. Allergy Immunol.* 111:362-365 (1996)
- 46 Fendly et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor" *Hybridoma* 6:359-369 (1987)
- 47 Fischer et al., "Role of the LFA-1 Molecule in Cellular Interactions Required For Antibody Production in Humans" *The Journal of Immunology* 136(9):3198-3203 (May 1, 1986)
- 48 Gao and Issekutz, "Mac-1 (CD11b/CD18) is the predominant β_2 (CD18) integrin mediating human neutrophil migration through synovial and dermal fibroblast barriers" *Immunology* 88:463-470 (1996)
- 49 Herve et al., "Monoclonal Anti α Antibody to the Treatment of Sever Acute GVHD in Humans" *Lymphoma Res.* (Abstract No. 3.25) 9:591 (1990)
- 50 Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" *European Journal of Immunology* 13:202-208 (1983)
- 51 Hirai et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor" *J. Immunol. Meth.* 96:57-62 (1987)
- 52 Howard et al., "Soluble Tumor Necrosis Factor Receptor: Inhibition of Human Immunodeficiency Virus Activation" *Proc. Natl. Acad. Sci. USA* 90:2335-2339 (1993)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED
JAN 23 2003
TECH CENTER 1800/2000



FORM PTO-144b

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738610

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 53 Isaacs et al., "Humanized anti-CD4 monoclonal antibody therapy of autoimmune and inflammatory diseases" Clinical & Experimental Immunology 110(2):158-166 (Nov 1997)
- 54 Ishikawa et al., "The Role of Adhesion Molecules in Synovial Pannus Formation in Rheumatoid Arthritis" Clinical Orthopaedics and Related Research 300:297-303 (1994)
- 55 Joosten et al., "IL-1 α Blockade Prevents Cartilage and Bone Destruction in Murine Type II Collagen-Induced Arthritis, Whereas TNF- α Blockade Only Ameliorates Joint Inflammation" Journal of Immunology 163:5049-5055 (1999)
- 56 Kremer, J.M., "Combination therapy with biological agents in rheumatoid arthritis: perils and promise" Arthritis and Rheumatism 41(9):1548-1551 (1998)
- 57 Krensky et al., "The Functional Significance, Distribution, and Structure of LFA-1, LFA-2, and LFA-3: Cell Surface Antigens Associated with CTL-Target Interactions" The Journal of Immunology 131(2):611-616 (August 1983)
- 58 Kuypers and Roos, "Leukocyte Membrane Adhesion Proteins LFA-1, CR3 and p150,95: A Review of Functional and Regulatory Aspects" Res. Immunol. 140:461-486 (1989)
- 59 Liang et al., "Production and characterization of monoclonal antibodies against recombinant human tumor necrosis factor/cachectin" Biochem. & Biophys. Res. Comm. 137:847-854 (1986)
- 60 Loetscher et al., "Molecular Cloning and Expression of the Human 55 Kd Tumor Necrosis Factor Receptor" Cell 61:351-359 (1990)
- 61 Lovell et al., "Safety and Efficacy of Tumor Necrosis Factor Receptor P75 FC Fusion Protein" Arthritis and Rheumatism (Abstract No. 584) 41(9):S130 (1998)
- 62 Maini et al., "Therapeutic efficacy of multiple intravenous infusions of anti-tumor necrosis factor α monoclonal antibody combined with low-dose weekly methotrexate in rheumatoid arthritis" Arthritis and Rheumatism 41(9):1552-1563 (1998)
- 63 Meager et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumor Necrosis Factor (rTNF)" Hybridoma 6:305-311 (1987)
- 64 Mohler et al., "Soluble tumor necrosis factor (TNF) receptors are effective therapeutic agents in lethal endotoxemia and function simultaneously as both TNF carriers and TNF antagonists" Journal of Immunology 151(3):1548-1561 (Aug 1, 1993)
- 65 Moller et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor α : In Vitro and In Vivo Application" Cytokine 2:162-169 (1990)
- 66 Moreland et al., "Etanercept Therapy in Rheumatoid Arthritis: A Randomized, Controlled Trial" Annals of Internal Medicine 130:478-486 (1999)
- 67 Moreland et al., "Longterm Treatment of DMARD Failing Rheumatoid Arthritis Patients with TNF Receptor P75 FC Fusion Protein" J. Invest. Med. (abstract only) 46:229A (1998)
- 68 Nakatsuka et al., "Rheumatoid Synovial Fibroblasts are Stimulated by the Cellular Adhesion to T Cells Through Lymphocyte Function Associated Antigen-1/Intercellular Adhesion Molecule-1" J. Rheumatology 24:458-464 (1997)
- 69 Nishimura et al., "The role of lymphokine-activated cell-associated antigen. III. Inhibition of T-cell activation by monoclonal killer-blocking antibody" Cellular Immunology 107(1):32-39 (Jun 1987)
- 70 Noppar et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type I TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor" EMBO Journal 9:3269-3278 (1990)
- 71 Peppel et al., "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity" Journal of Experimental Medicine 174:1483-1489 (1991)
- 72 Sanchez-Madrid et al., "Mapping of antigenic and functional epitopes on the α - and β -subunits of two related mouse glycoproteins involved in cell interactions, LFA-1 and MAC-1" Journal of Experimental Medicine 158(2):586-602 (Aug 1, 1983)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P1795R1Serial No.
09/738,540

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Lee et al.Filing Date
14 Dec 2000Group
1644

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- | | |
|----|---|
| 73 | Schall et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor" <i>Cell</i> 61:361-370 (1990) |
| 74 | Seckinger et al., "A Human Inhibitor of Tumor Necrosis Factor α " <i>Journal of Experimental Medicine</i> 167:1511-1516 (1988) |
| 75 | Spencer-Green, G., "Etanercept (Enbrel): update on therapeutic use" <i>Ann. Rheum. Dis.</i> 59:146-149 (2000) |
| 76 | Springer et al., "LFA-1 and L γ 2-3, molecules associated with T lymphocyte-mediated killing; and Mac-1, an LFA-1 homologue associated with complement receptor function" <i>Immunol. Rev.</i> 68:171-195 (1982) |
| 77 | Springer et al., "The lymphocyte function-associated LFA-1, CD2, and LFA-3 molecules: cell adhesion receptors of the immune system" <i>Annual Review of Immunology</i> 5:223-252 (1987) |
| 78 | Strand et al., "Biological Agents for the Treatment of Rheumatoid Arthritis" <i>Clinical Immunology and the Rheumatologist</i> 22(1):117-132 (1996) |
| 79 | Taylor et al., "The expression of CD18 is increased on Trisomy 21 (Down syndrome) lymphoblastoid cells" <i>Clinical & Experimental Immunology</i> 71(2):324-328 (Feb 1988) |
| 80 | Ulich et al., "Short Communication: Intratracheal Administration of Endotoxin and Cytokines IV. The Soluble Tumor Necrosis Factor Receptor Type I Inhibits Acute Inflammation" <i>American Journal of Pathology</i> 142(5):1335-1338 (1993) |
| 81 | Weinblatt et al., "A Trial of Etanercept, a Recombinant Tumor Necrosis Factor Receptor: Fc Fusion Protein, in Patients with Rheumatoid Arthritis Receiving Methotrexate" <i>New England J. of Medicine</i> 340(4):253-259 (1999) |
| 82 | Williams et al., "Anti-tumor necrosis factor ameliorates joint disease in murine collagen-induced arthritis" <i>Proc. Natl. Acad. Sci. USA</i> 89:9784-9788 (1992) |
| 83 | Williams et al., "Synergy between anti-CD4 and anti-tumor necrosis factor in the amelioration of established collagen-induced arthritis" <i>Proc. Natl. Acad. Sci. USA</i> 91:2762-2766 (1994) |
| 84 | Williams, R.O., "Combination therapy in mice: what can we learn that may be useful for understanding rheumatoid arthritis" <i>Springer Seminars in Immunopathology</i> 20:165-180 (1998) |
| 85 | Woolley et al., "Influence of a Recombinant Human Soluble Tumor Necrosis Factor Receptor Fc Fusion Protein on Type II Collagen-Induced Arthritis In Mice" <i>The Journal of Immunology</i> 151(11):6602-6607 (1993) |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED
JAN 8 2003
TECH CENTER 1800/1800